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Applicants: Hans Josef Stauss and Persis Jal Amrolia

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Serial No.:

10/003,983

Art Unit:

1645

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TECH CENTER 1600/2900

Filed:

October 31, 2001

Examiner:

Not Yet Assigned

For:

IMMUNOTHERAPEUTIC METHODS AND MOLECULES

Assistant Commissioner for Patents Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including four (4) pages of Form PTO-1449 and a copy of each document cited therein.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

U.S. Patents

Number	Issue Date	<u>Patentee</u>	Class/Subclass
4,690,915	09-01-1987	Rosenberg	514/2
4,844,893	07-04-1989	Honsik et al.	424/85.8
6,060,054	05-09-2000	Staerz	424/134.1

U.S.S.N.: 10/003,983

Filed: October 31, 2001

INFORMATION DISCLOSURE STATEMENT

Foreign Documents

Number	Publication Date	Patentee	Country
WO 93/17095	09-02-1993	Scripps Research Institute	PCT
WO 92/13887	08-20-1992	The Victoria	PCT
		University of Manchester	
WO 97/26328	07-24-1997	RPMS Technology Limited	PCT
WO 00/02922 A1	01-20-2000	Fuso Pharmaceutical	PCT'
		Industries, Ltd	
WO 00/26249 A1	05-11-2000	Imperial College	PCT
		Innovations Limited	

• Publications

AMROLIA, et al., "Nonmyeloablative stem cell transplantation for congenital immunodeficiencies," Blood 96(4):1239-1247 (2000).

CHUNG, et al., "Functional three-domain single-chain T-cell receptors," Proc. Natl. Acad. Sci. USA 91:12654-12658 (1994).

ELVIN, et al., "A method to quantify binding of unlabeled peptides to class I MHC molecules and detect their allele specificity," J. Immunol. Methods 158:161-171 (1993).

ESHHAR, et al., "Specific activation and targeting of cytotoxic lymphocytes through chimeric single chains consisting of antibody-binding domains and the γ or ξ subunits of the immunoglobulin and T-cell receptors," Proc. Natl. Acad. Sci. USA 90:720-724 (1993).

FINER, et al., "kat: A High-Efficiency Retroviral Transduction System for Primary Human T Lymphocytes," Blood 83:43 (1994).

HANDGRETINGER, et al., "Transplantation of Megadoses of Purified Haploidentical Stem Cells," Ann. NY Acad. Sci. 8972:351-361 (1999).

HWU, et al., "Lysis of Ovarian Cancer Cells by Human Lymphocytes Redirected with a Chimeric Gene Composed of an Antibody Variable Region and the Fc Receptor γ chain," J. Exp. Med 178:361-366 (1993).

JACKSON, et al., "Empty and peptide-containing conformers of class I major histocompatibility complex molecules expressed in Drosophila melanogaster cells," Proc. Natl. Acad. Sci. USA 89:12117 (1992).

KAST, et al., "Eradication of Adenovirus E1-Induced Tumors by E1A-Specific Cytotoxic T Lumphocytes," Cell 59:603-614 (1989).

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Filed:

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INFORMATION DISCLOSURE STATEMENT

KAWAKAMI, et al., "Identification of a human melanoma antigen recognized by tumorinfiltrating lymphocytes associated with in vivo tumor rejection," Proc. Natl. Acad. Sci. USA 91:6458-6462 (1994).

KIM, et al., "Introduction of Soluble Proteins into the MHC Class I Pathway by Conjugation to an HIV tat Peptide," J. Immunol. 159:1666-1668 (1997).

LJUNGGREN & KARRE, "Host Resistance Directed Selectively Against H-2-Deficient Lymphoma Variants," J. Exp. Med. 162:1745 (1985).

LU, et al., "Improved Synthesis of 4-Alkoxybenzyl Alcohol Resin," J. Org. Chem. 46:3433 (1981).

MÉZIÈRE, et al., "In Vivo T Helper Cell Response to Retro-Inverso Peptidomimetics," J. Immunol. 159:3230-3237 (1997).

MORITZ, et al., Cytotoxic T lymphocytes with a grafted recognition specificity for ERBB2-expressing tumor cells," Proc. Natl. Acad. Sci. USA 91:4318-4322 (1994).

MOTTEZ, et al., "Cells Expressing a Major Histocompatibility Complex Class I Molecule with a Signle Covalently Bound Peptide Are Highly Immunogenic," J. Exp. Med. 181:493-502 (1995).

PORTA, et al., "Development of Cowpea Mosaic Virus as a High-Yielding System for the Presentation of Foreign Peptides," Virology 202:449-955 (1994).

ROBERTS, et al., "Targeting of Human Immunodeficiency Virus-Infected Cells by CD8 T Lymphocytes Armed With Universal T-Cell Receptors," Blood 84:2878-2889 (1994).

SAIKI, et al., "Primer-Directed Enzymatic Amplification of DNA with a Thermostable DNA Polymerase," Science 239:487-491 (1988).

The Leukocyte Antigen Fact Book, 2nd edition, "CD45: Leucocyte common antigen (L-CA), B220, T200, Ly-5, EC 3.1.3.48," pp. 244-247, Academic Press, Harcourt, Brace & Co. (publishers), 1997.

TOURDOT, et al., "Chimeric Peptides: A New Approach to Enhancing the Immunogenicity of Peptides with Low MHC Class I Affinity," J. Immunol. 159:2391-2398 (1997).

WILSON, et al., "Immunogenicity. I. Use of Peptide Libraries to Identify Epitopes That Activate Clonotypic CD4 T Cells and Induce T Cell Responses to Native Peptide Ligands," J. Immunol. 163:6424-6434 (1999).

U.S.S.N.:

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Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicant are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,

Patrea Il. Pabst

Reg. No. 31,284

Dated: April 19, 2002

HOLLAND & KNIGHT LLP One Atlantic Center 1201 West Peachtree Street, N.E. Suite 2000 Atlanta, Georgia 30309-3400 404-817-8473 FAX 404-817-8588 www.hklaw.com U.S.S.N.:

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number Substitute for form 1449A/PTO Complete if Known Application Number 10/003,983 **INFORMATION DISCLOSURE** APR 23 2002 TATEMENT BY APPLICANT TECH CENTER 1600/2900 (use as many sheets as necessary) Filing Date October 31, 2001 First Named Inventor Hans Josef Stauss **Group Art Unit** 1645 **Examiner Name** of 4 Attorney Docket Number ICI 103

	U.S. PATENT DOCUMENTS							
Examiner Cite No.1	US Patent Documen		Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear				
		Number Kind Coo (if know						
		4,690,915	Rosenberg	09-01-1987				
		4,844,893	Honsik et al.	07-04-1989				
		6,060,054	Staerz	05-09-2000				
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	wo	00/02922	A1	Fuso Pharmaceutical Industries, Ltd	01-20-2000		
	WO	00/26249	A1	Imperial College Innovations Limited	05-11-2000		
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(1989).

					Patent and Trademark (Office: U.S. DEPARTMENT OF C	OMMERCE
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AMROLIA, et al., "Nonmyeloablative stem of (2000). CHUNG, et al., "Functional three-domain signs"		publisher, city and/or country where page cell transplantation for congenite	oublished al immunodeficiencies," oc. Natl. Acad. Sci. USA	Blood 96(4):1239-1247			
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	H/ 89	ANDGRETINGER, et a 972:351-361 (1999).	al., "Transplantation	of Megadoses of Purified Haple	oidentical Stem Cells,"	Ann. NY Acad. Sci.	

Examiner's Signature	Date Considered
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HWU, et al., "Lysis of Ovarian Cancer Cells by Human Lymphocytes Redirected with a Chimeric Gene Composed of an

KAST, et al., "Eradication of Adenovirus E1-Induced Tumors by E1A-Specific Cytotoxic T Lumphocytes," Cell 59:603-614

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JACKSON, et al., "Empty and peptide-containing conformers of class I major histocompatibility complex molecules

Antibody Variable Region and the Fc Receptor γ chain," J. Exp. Med 178:361-366 (1993).

expressed in Drosophila melanogaster cells," Proc. Natl. Acad. Sci. USA 89:12117 (1992).

with in vivo tumor rejection," Proc. Natl. Acad. Sci. USA 91:6458-6462 (1994).

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		KIM, et al., "Introduction of Soluble Proteins Immunol. 159:1666-1668 (1997).	ns into the MHC Class I Pathway by Conjugation to an HIV tat Peptide," J.				
		LJUNGGREN & KARRE, "Host Resistance 162:1745 (1985).	Directed Selectively Against H-2-Deficient Lyn	nphoma Variants," J. Exp. Med.			
		LU, et al., "Improved Synthesis of 4-Alkoxyt	enzyl Alcohol Resin," J. Org. Chem. 46:3433	(1981).			
		MÉZIÈRE, et al., "In Vivo T Helper Cell Res	ponse to Retro-Inverso Peptidomimetics," J. II	mmunol. 159:3230-3237 (1997).			
		MORITZ, et al., Cytotoxic T lymphocytes wi Acad. Sci. USA 91:4318-4322 (1994).	th a grafted recognition specificity for ERBB2-	expressing tumor cells," Proc. Natl.			
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		ROBERTS, et al., "Targeting of Human Imm Universal T-Cell Receptors," <i>Blood</i> 84:2878	nunodeficiency Virus-Infected Cells by CD8 T (-2889 (1994).	Lymphocytes Armed With			
!		SAIKI, et al., "Primer-Directed Enzymatic Al 491 (1988).	nplification of DNA with a Thermostable DNA	Polymerase," Science 239:487-			
		The Leukocyte Antigen Fact Book, 2nd edition	n, "CD45: Leucocyte common antigen (L-CA)	, B220, T200, Ly-5, EC 3.1.3.48,"			

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pp. 244-247, Academic Press, Harcourt, Brace & Co. (publishers), 1997.

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Filing Date First Named Inventor

Group Art Unit

October 31, 2001

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Hans Josef Stauss

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